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Attorneys for Defendants Lupin Pharmaceuticals, Inc. and Lupin Ltd.

# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

SEPRACOR INC.,

Plaintiff,

٧.

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD., WOCKHARDT LTD., WOCKHARDT USA, INC., DR. REDDY'S LABORATORIES, LTD., DR. REDDY'S LABORATORIES, INC., ROXANE LABORATORIES, INC., COBALT LABORATORIES INC., COBALT PHARMACEUTICALS INC., GLENMARK GENERICS INC., USA, GLENMARK GENERICS, LTD., GLENMARK PHARMACEUTICALS, LTD., ORCHID HEALTHCARE (a Division of ORCHID CHEMICALS & PHARMACEUTICALS, LTD.), ORCHID CHEMICALS & PHARMACEUTICALS, LTD., ORGENUS PHARMA INC., LUPIN PHARMACEUTICALS, INC., LUPIN LTD.. SUN PHARMA GLOBAL INC., SUN PHARMACEUTICAL INDUSTRIES INC., SUN PHARMACEUTICAL INDUSTRIES LTD., ALPHAPHARM PTY. LTD. AND MYLAN, INC.,

Defendants.

Civil Action. No.: 09-cv-01302 (DMC) (MF)

DOCUMENT FILED ELECTRONICALLY

ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS OF DEFENDANTS LUPIN PHARMACEUTICALS, INC. AND LUPIN LTD Defendants Lupin Pharmaceuticals, Inc. and Lupin Ltd. (collectively "Lupin" or "Defendants") by their undersigned counsel, for their Answer and Counterclaims to the Complaint for Patent Infringement of Sepracor Inc. ("Sepracor" or "Plaintiff"), state and allege as follows:

## The Parties

- 1.A. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1.A of the Complaint, and, therefore, deny them.
- 1.B. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1.B of the Complaint, and, therefore, deny them.
- 1.C. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1.C of the Complaint, and, therefore, deny them.
- 1.D. On information and belief, Defendants admit the allegations set forth in paragraph 1.D of the Complaint.
- 1.E. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1.E of the Complaint, and, therefore, deny them.
- 1.F. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1.F of the Complaint, and, therefore, deny them.
- 1.G. On information and belief, Defendants admit the allegations set forth in paragraph 1.G of the Complaint.

- 1.H. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1.H of the Complaint, and, therefore, deny them.
- 1.I. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1.1 of the Complaint, and, therefore, deny them.
- 1.J. On information and belief, Defendants admit the allegations set forth in paragraph

  1.J of the Complaint.
- 1.K. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1.K of the Complaint, and, therefore, deny them.
- 1.L. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1.L of the Complaint, and, therefore, deny them.
- 1.M. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1.M of the Complaint, and, therefore, deny them.
- 1.N. On information and belief, Defendants admit the allegations set forth in paragraph

  1.N of the Complaint.
- 1.O. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1.O of the Complaint, and, therefore, deny them.
- 1.P. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1.P of the Complaint, and, therefore, deny them.

- 1.Q. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1.Q of the Complaint, and, therefore, deny them.
- 1.R. On information and belief, Defendants admit the allegations set forth in paragraph
  1.R of the Complaint.
- 1.S. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1.S of the Complaint, and, therefore, deny them.
- 1.T. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1.T of the Complaint, and, therefore, deny them.
- 1.U. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1.U of the Complaint, and, therefore, deny them.
- 1.V. On information and belief, Defendants admit the allegations set forth in paragraph 1.V of the Complaint.
- 1.W. Lupin Ltd. and Lupin Pharmaceuticals, Inc. ("Lupin Pharma") admit that Lupin Pharma is a Virginia corporation and a wholly-owned subsidiary of Lupin Ltd., and that it has a place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland, 21202. Lupin Pharma further admits that it distributes generic drugs for sale and use throughout the United States, including in this judicial district. Lupin Ltd. and Lupin Pharma deny the remaining allegations made in paragraph 1.W of the Complaint.
- 1.X Lupin Ltd. and Lupin Pharma admit that Lupin Ltd. is a corporation organized and existing under the laws of India, with a place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India, and with its only places of

business located in India; that Lupin Ltd. develops, manufactures, markets and sells pharmaceutical products, including generic pharmaceutical products; and that Lupin Pharma distributes pharmaceutical products, including generic pharmaceutical products manufactured by Lupin Ltd. that have been authorized by the United States Food and Drug Administration under applicable law. Lupin Ltd. and Lupin Pharma deny the remaining allegations made in paragraph 1.X of the Complaint.

- 1.Y. Defendants admit the allegations set forth in paragraph 1.Y of the Complaint.
- 1.Z. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1.Z of the Complaint, and, therefore, deny them.
- 1.AA. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1.AA of the Complaint, and, therefore, deny them.
- 1.BB. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1.BB of the Complaint, and, therefore, deny them.
- 1.CC. On information and belief, Defendants admit the allegations set forth in paragraph 1.CC of the Complaint.
- 1.DD. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1.DD of the Complaint, and, therefore, deny them.

- 1.EE. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1.EE of the Complaint, and, therefore, deny them.
- 1.FF. On information and belief, Defendants admit the allegations set forth in paragraph1.FF of the Complaint.

## Jurisdiction and Venuc

- 2. Defendants admit the allegations set forth in paragraph 2 of the Complaint.
- 3. Lupin Ltd. and Lupin Pharma admit that this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a). Lupin Ltd. does not contest personal jurisdiction or venue in this District, solely for the purposes of this action. Lupin Pharma admits that, as to it, venue is proper in this District.
- 4. Lupin Pharma admits that this Court has personal jurisdiction over it. Lupin Ltd. does not contest personal jurisdiction or venue in this District, solely for the purposes of this action. Lupin Pharma and Lupin Ltd. further aver that they informed Plaintiff, through counsel and prior to filing of any Complaint by Plaintiff, that they would not contest personal jurisdiction or venue in this District. Lupin Pharma and Lupin Ltd. deny that they have committed, aided, abetted, contributed to and/or participated in the commission of a tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiff. Defendants are without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in paragraph 4 of the Complaint, and, therefore, deny them.
- 5. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 5 of the Complaint, and, therefore, deny them.

- 6. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 6 of the Complaint, and, therefore, deny them.
- 7. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 7 of the Complaint, and, therefore, deny them.
- 8. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 8 of the Complaint, and, therefore, deny them.
- 9. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 9 of the Complaint, and, therefore, deny them.
- 10. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 10 of the Complaint, and, therefore, deny them.
- 11. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 11 of the Complaint, and, therefore, deny them.
- 12. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 12 of the Complaint, and, therefore, deny them.
- 13. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 13 of the Complaint, and, therefore, deny them.
- 14. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 14 of the Complaint, and, therefore, deny them.
- 15. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 15 of the Complaint, and, therefore, deny them.
- 16. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 16 of the Complaint, and, therefore, deny them.

- 17. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 17 of the Complaint, and, therefore, deny them.
- 18. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 18 of the Complaint, and, therefore, deny them.
- 19. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 19 of the Complaint, and, therefore, deny them.
- 20. Defendants admit that an email dated March 16, 2009 stated that Lupin Pharma would not object to personal jurisdiction and venue in this judicial district only for the purposes of this case predicated upon the filing of the Lupin ANDA relating to eszopiclone. Defendants deny the remaining allegations set forth in paragraph 20 of the Complaint.
- 21. Defendants admit that an email dated March 16, 2009 stated that Lupin Ltd. would not object to personal jurisdiction and venue in this judicial district only for the purposes of this case predicated upon the filing of the Lupin ANDA relating to eszopiclone. Defendants deny the remaining allegations set forth in paragraph 21 of the Complaint.
- 22. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 22 of the Complaint, and, therefore, deny them.
- 23. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 23 of the Complaint, and, therefore, deny them.
- 24. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 24 of the Complaint, and, therefore, deny them.
- 25. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 25 of the Complaint, and, therefore, deny them.

26. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 26 of the Complaint, and, therefore, deny them.

## The Patents

- 27. Defendants admit that the issue date set forth on the face of the '257 patent titled "Optically Active 5H-Pyrrolo[3,4-B] Pyrazine Derivative, Its Preparation and Pharmaceutical Compositions Containing It," is March 8, 2005 and that the assignce listed on the face of the '257 patent is Sepracor, Inc. Defendants further admit that a copy of the '257 patent was attached to the Complaint. Defendants deny that the '257 patent was "duly and legally" issued by the United States Patent and Trademark Office. On information and belief, Defendants admit the remaining allegations set forth in paragraph 27 of the Complaint.
- 28. Defendants admit that the issue date set forth on the face of the '673 patent titled "Optically Active 5H-Pyrrolo[3,4-B] Pyrazine Derivative, Its Preparation and Pharmaceutical Compositions Containing It," is September 3, 2002 and that the assignee listed on the face of the '673 patent is Sepracor Inc. Defendants further admit that a copy of the '673 patent was attached to the Complaint. Defendants deny that the '673 patent was "duly and legally" issued by the United States Patent and Trademark Office. On information and belief, Defendants admit the remaining allegations set forth in paragraph 28 of the Complaint.
- 29. Defendants admit that the issue date set forth on the face of the '926 patent titled "Optically Active 5H-Pyrrolo[3,4-B] Pyrazine Derivative, Its Preparation and Pharmaceutical Compositions Containing It," is November 20, 2001 and that the assignee listed on the face of the '926 patent is Sepracor Inc. Defendants further admit that a copy of the '926 patent was attached to the Complaint. Defendants deny that the '926 patent was "duly and legally" issued

by the United States Patent and Trademark Office. On information and belief, Defendants admit the remaining allegations set forth in paragraph 29 of the Complaint.

30. Defendants admit that the issue date set forth on the face of the '724 patent titled 'Optically Active 5H-Pyrrolo[3,4-B] Pyrazine Derivative, Its Preparation and Pharmaceutical Compositions Containing Same," is June 3, 2008 and that the assignee listed on the face of the '724 patent is Sepracor Inc. Defendants further admit that a copy of the '724 patent was attached to the Complaint. Defendants deny that the '724 patent was "duly and legally" issued by the United States Patent and Trademark Office. On information and belief, Defendants admit the remaining allegations set forth in paragraph 30 of the Complaint.

## Acts Giving Rise to This Action

## Infringement of the '257 Patent

#### COUNT I – INFRINGEMENT OF THE '257 PATENT BY TEVA

- 31. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 30 of the Complaint as if fully set forth herein.
- 32. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 32 of the Complaint, and, therefore, deny them.
- 33. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 33 of the Complaint, and, therefore, deny them.
- 34. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 34 of the Complaint, and, therefore, deny them.
- 35. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 35 of the Complaint, and, therefore, deny them.

- 36. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 36 of the Complaint, and, therefore, deny them.
- 37. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 37 of the Complaint, and, therefore, deny them.
- 38. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 38 of the Complaint, and, therefore, deny them.
- 39. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 39 of the Complaint, and, therefore, deny them.

## COUNT II – INFRINGEMENT OF THE '257 PATENT BY REDDY

- 40. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 39 of the Complaint as if fully set forth herein.
- 41. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 41 of the Complaint, and, therefore, deny them.
- 42. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 42 of the Complaint, and, therefore, deny them.
- 43. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 43 of the Complaint, and, therefore, deny them,
- 44. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 44 of the Complaint, and, therefore, deny them.
- 45. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 45 of the Complaint, and, therefore, deny them.
- 46. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 46 of the Complaint, and, therefore, deny them.

- 47. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 47 of the Complaint, and, therefore, deny them.
- 48. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 48 of the Complaint, and, therefore, deny them.

## COUNT III - INFRINGEMENT OF THE '257 PATENT BY ROXANE

- 49. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 48 of the Complaint as if fully set forth herein.
- 50. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 50 of the Complaint, and, therefore, deny them.
- 51. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 51 of the Complaint, and, therefore, deny them.
- 52. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 52 of the Complaint, and, therefore, deny them.
- 53. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 53 of the Complaint, and, therefore, deny them.
- 54. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 54 of the Complaint, and, therefore, deny them.
- 55. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 55 of the Complaint, and, therefore, deny them.
- 56. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 56 of the Complaint, and, therefore, deny them.

#### COUNT IV - INFRINGEMENT OF THE '257 PATENT BY COBALT

- 57. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 56 of the Complaint as if fully set forth herein.
- 58. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 58 of the Complaint, and, therefore, deny them.
- 59. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 59 of the Complaint, and, therefore, deny them.
- 60. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 60 of the Complaint, and, therefore, deny them.
- 61. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 61 of the Complaint, and, therefore, deny them.
- 62. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 62 of the Complaint, and, therefore, deny them.
- 63. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 63 of the Complaint, and, therefore, deny them.
- 64. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 64 of the Complaint, and, therefore, deny them.
- 65. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 65 of the Complaint, and, therefore, deny them.

#### COUNT V – INFRINGEMENT OF THE '257 PATENT BY GLENMARK

66. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 65 of the Complaint as if fully set forth herein.

- 67. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 67 of the Complaint, and, therefore, deny them.
- 68. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 68 of the Complaint, and, therefore, deny them.
- 69. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 69 of the Complaint, and, therefore, deny them.
- 70. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 70 of the Complaint, and, therefore, deny them.
- 71. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 71 of the Complaint, and, therefore, deny them.
- 72. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 72 of the Complaint, and, therefore, deny them.
- 73. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 73 of the Complaint, and, therefore, deny them.
- 74. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 74 of the Complaint, and, therefore, deny them.

## COUNT VI - INFRINGEMENT OF THE '257 PATENT BY ORCHID

- 75. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 74 of the Complaint as if fully set forth herein.
- 76. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 76 of the Complaint, and, therefore, deny them.
- 77. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 77 of the Complaint, and, therefore, deny them.

- 78. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 78 of the Complaint, and, therefore, deny them.
- 79. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 79 of the Complaint, and, therefore, deny them.
- 80. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 80 of the Complaint, and, therefore, deny them.
- 81. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 81 of the Complaint, and, therefore, deny them.
- 82. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 82 of the Complaint, and, therefore, deny them.
- 83. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 65 of the Complaint, and, therefore, deny them.

## COUNT VII - INFRINGEMENT OF THE '257 PATENT BY LUPIN

- 84. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 83 of the Complaint as if fully set forth herein.
- 85. Defendants admit that ANDA No. 91-124 was submitted by Lupin Ltd. to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(j)), and that ANDA No. 91-124 seeks FDA approval for the commercial manufacture, use and sale of generic tablets containing 1 mg, 2 mg, or 3 mg of eszopiclone ("the ANDA products") prior to the expiration of the '257 patent. Defendants admit that ANDA No. 91-124 seeks to market the ANDA products prior to the expiration of the '257 patent, and that the ANDA contained a certification with respect to that patent. Defendants deny the remaining allegations set forth in paragraph 85 of the complaint.

- 86. Defendants admit that ANDA No. 91-124 contains a certification pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '257 patent are either invalid or will not be infringed by the manufacture, use or sale of the proposed generic versions of Sepracor's Lunesta® brand products. Defendants admit that on or about February 23, 2009, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Lupin Ltd. sent a statement to Sepracor, in which Lupin Ltd. represented that it had filed ANDA No. 91-124, seeking to market the ANDA Products prior to the expiration of the '257 patents, and that its ANDA contained a certification with respect to that patent. Defendants deny the remaining allegations set forth in paragraph 86 of the complaint.
  - 87. Defendants deny the allegations set forth in paragraph 87 of the complaint.
  - 88. Defendants deny the allegations set forth in paragraph 88 of the complaint.
  - 89. Defendants deny the allegations set forth in paragraph 89 of the complaint.
- 90. Defendants admit that at the time the certification in paragraph 86 was filed with the FDA, Lupin Ltd. and Lupin Pharma were aware of the existence of the '257 patent.

  Defendants deny the remaining allegations set forth in paragraph 90 of the complaint.
  - 91. Defendants deny the allegations set forth in paragraph 91 of the complaint.
  - 92. Defendants deny the allegations set forth in paragraph 92 of the complaint.

## COUNT VIII - INFRINGEMENT OF THE '257 PATENT BY SUN

- 93. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 92 of the Complaint as if fully set forth herein.
- 94. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 94 of the Complaint, and, therefore, deny them.

- 95. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 95 of the Complaint, and, therefore, deny them.
- 96. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 96 of the Complaint, and, therefore, deny them.
- 97. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 97 of the Complaint, and, therefore, deny them.
- 98. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 98 of the Complaint, and, therefore, deny them.
- 99. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 99 of the Complaint, and, therefore, deny them.
- 100. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 100 of the Complaint, and, therefore, deny them.
- 101. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 101 of the Complaint, and, therefore, deny them.

## COUNT IX - INFRINGEMENT OF THE '257 PATENT BY ALPHAPHARM

- 102. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 101 of the Complaint as if fully set forth herein.
- 103. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 103 of the Complaint, and, therefore, deny them.

- 104. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 104 of the Complaint, and, therefore, deny them.
- 105. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 105 of the Complaint, and, therefore, deny them.
- 106. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 106 of the Complaint, and, therefore, deny them.
- 107. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 107 of the Complaint, and, therefore, deny them.
- 108. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 108 of the Complaint, and, therefore, deny them.
- 109. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 109 of the Complaint, and, therefore, deny them.
- 110. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 110 of the Complaint, and, therefore, deny them.

# Infringement of the '673 Patent

## COUNT X - INFRINGEMENT OF THE '673 PATENT BY WOCKHARDT

- 111. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 110 of the Complaint as if fully set forth herein.
- 112. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 112 of the Complaint, and, therefore, deny them.
- 113. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 113 of the Complaint, and, therefore, deny them.
- 114. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 114 of the Complaint, and, therefore, deny them.
- 115. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 115 of the Complaint, and, therefore, deny them.
- 116. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 116 of the Complaint, and, therefore, deny them.
- 117. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 117 of the Complaint, and, therefore, deny them.

- 118. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 118 of the Complaint, and, therefore, deny them.
- 119. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 119 of the Complaint, and, therefore, deny them.

## COUNT XI – INFRINGEMENT OF THE '673 PATENT BY REDDY

- 120. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 119 of the Complaint as if fully set forth herein.
- 121. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 121 of the Complaint, and, therefore, deny them.
- 122. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 122 of the Complaint, and, therefore, deny them.
- 123. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 123 of the Complaint, and, therefore, deny them.
- 124. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 124 of the Complaint, and, therefore, deny them.

- 125. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 125 of the Complaint, and, therefore, deny them.
- 126. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 126 of the Complaint, and, therefore, deny them.
- 127. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 127 of the Complaint, and, therefore, deny them.
- 128. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 128 of the Complaint, and, therefore, deny them.

#### COUNT XII – INFRINGEMENT OF THE '673 PATENT BY ROXANE

- 129. Defendants repeat and reassert their answers to the allegations set forth in paragraphs I through 128 of the Complaint as if fully set forth herein.
- 130. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 130 of the Complaint, and, therefore, deny them.
- 131. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 131 of the Complaint, and, therefore, deny them.

- 132. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 132 of the Complaint, and, therefore, deny them.
- 133. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 133 of the Complaint, and, therefore, deny them.
- 134. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 134 of the Complaint, and, therefore, deny them.
- 135. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 135 of the Complaint, and, therefore, deny them.
- 136. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 136 of the Complaint, and, therefore, deny them.

## COUNT XIII – INFRINGEMENT OF THE '673 PATENT BY COBALT

- 137. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 136 of the Complaint as if fully set forth herein.
- 138. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 138 of the Complaint, and, therefore, deny them.

- 139. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 139 of the Complaint, and, therefore, deny them.
- 140. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 140 of the Complaint, and, therefore, deny them.
- 141. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 141 of the Complaint, and, therefore, deny them.
- 142. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 142 of the Complaint, and, therefore, deny them.
- 143. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 143 of the Complaint, and, therefore, deny them.
- 144. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 144 of the Complaint, and, therefore, deny them.
- 145. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 145 of the Complaint, and, therefore, deny them.

## COUNT XIV - INFRINGEMENT OF THE '673 PATENT BY GLENMARK

- 146. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 145 of the Complaint as if fully set forth herein.
- 147. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 147 of the Complaint, and, therefore, deny them.
- 148. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 148 of the Complaint, and, therefore, deny them.
- 149. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 149 of the Complaint, and, therefore, deny them.
- 150. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 150 of the Complaint, and, therefore, deny them.
- 151. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 151 of the Complaint, and, therefore, deny them.
- 152. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 152 of the Complaint, and, therefore, deny them.

- 153. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 153 of the Complaint, and, therefore, deny them.
- 154. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 154 of the Complaint, and, therefore, deny them.

## COUNT XV - INFRINGEMENT OF THE '673 PATENT BY ORCHID

- 155. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 154 of the Complaint as if fully set forth herein.
- 156. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 156 of the Complaint, and, therefore, deny them.
- 157. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 157 of the Complaint, and, therefore, deny them.
- 158. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 158 of the Complaint, and, therefore, deny them.
- 159. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 159 of the Complaint, and, therefore, deny them.

- 160. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 160 of the Complaint, and, therefore, deny them.
- 161. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 161 of the Complaint, and, therefore, deny them.
- 162. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 162 of the Complaint, and, therefore, deny them.
- 163. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 163 of the Complaint, and, therefore, deny them.

#### COUNT XVI – INFRINGEMENT OF THE '673 PATENT BY LUPIN

- 164. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 163 of the Complaint as if fully set forth herein.
- 165. Defendants admit that ANDA No. 91-124 was submitted by Lupin Ltd. to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(j)), and that ANDA No. 91-124 seeks FDA approval for the commercial manufacture, use and sale of generic tablets containing 1 mg, 2 mg, or 3 mg of eszopiclone ("the ANDA products") prior to the expiration of the '673 patent. Defendants admit that ANDA No. 91-124 seeks to market the ANDA products prior to the expiration of the '673 patent, and that the ANDA contained a certification with respect to that patent. Defendants deny the remaining allegations set forth in paragraph 165 of the complaint.

- 166. Defendants admit that ANDA No. 91-124 contains a certification pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '673 patent are either invalid or will not be infringed by the manufacture, use or sale of the proposed generic versions of Sepracor's Lunesta® brand products. Defendants admit that on or about February 23, 2009, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Lupin Ltd. sent a statement to Sepracor, in which Lupin Ltd. represented that it had filed ANDA No. 91-124, seeking to market the ANDA Products prior to the expiration of the '673 patents, and that its ANDA contained a certification with respect to that patent. Defendants deny the remaining allegations set forth in paragraph 166 of the complaint.
  - 167. Defendants deny the allegations set forth in paragraph 167 of the complaint.
  - 168. Defendants deny the allegations set forth in paragraph 168 of the complaint.
  - 169. Defendants deny the allegations set forth in paragraph 169 of the complaint.
- 170. Defendants admit that at the time the certification in paragraph 166 was filed with the FDA, Lupin Ltd. and Lupin Pharma were aware of the existence of the '673 patent.

  Defendants deny the remaining allegations set forth in paragraph 170 of the complaint.
  - 171. Defendants deny the allegations set forth in paragraph 171 of the complaint.
  - 172. Defendants deny the allegations set forth in paragraph 172 of the complaint.

## COUNT XVII - INFRINGEMENT OF THE '673 PATENT BY SUN

- 173. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 172 of the Complaint as if fully set forth herein.
- 174. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 174 of the Complaint, and, therefore, deny them.

- 175. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 175 of the Complaint, and, therefore, deny them.
- 176. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 176 of the Complaint, and, therefore, deny them.
- 177. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 177 of the Complaint, and, therefore, deny them.
- 178. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 178 of the Complaint, and, therefore, deny them.
- 179. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 179 of the Complaint, and, therefore, deny them.
- 180. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 180 of the Complaint, and, therefore, deny them.
- 181. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 181 of the Complaint, and, therefore, deny them.

## COUNT XVIII - INFRINGEMENT OF THE '673 PATENT BY ALPHAPHARM

- 182. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 181 of the Complaint as if fully set forth herein
- 183. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 183 of the Complaint, and, therefore, deny them.
- 184. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 184 of the Complaint, and, therefore, deny them.
- 185. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 185 of the Complaint, and, therefore, deny them.
- 186. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 186 of the Complaint, and, therefore, deny them.
- 187. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 187 of the Complaint, and, therefore, deny them.
- 188. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 188 of the Complaint, and, therefore, deny them.

- 189. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 189 of the Complaint, and, therefore, deny them.
- 190. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 190 of the Complaint, and, therefore, deny them.

## Infringement of the '926 Patent

## COUNT XIX - INFRINGEMENT OF THE '926 PATENT BY REDDY

- 191. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 190 of the Complaint as if fully set forth herein.
- 192. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 192 of the Complaint, and, therefore, deny them.
- 193. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 193 of the Complaint, and, therefore, deny them.
- 194. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 194 of the Complaint, and, therefore, deny them.
- 195. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 195 of the Complaint, and, therefore, deny them.

- 196. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 196 of the Complaint, and, therefore, deny them.
- 197. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 197 of the Complaint, and, therefore, deny them.
- 198. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 198 of the Complaint, and, therefore, deny them.
- 199. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 199 of the Complaint, and, therefore, deny them.

## COUNT XX - INFRINGEMENT OF THE '926 PATENT BY ROXANE

- 200. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 199 of the Complaint as if fully set forth herein.
- 201. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 201 of the Complaint, and, therefore, deny them.
- 202. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 202 of the Complaint, and, therefore, deny them.

- 203. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 203 of the Complaint, and, therefore, deny them.
- 204. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 204 of the Complaint, and, therefore, deny them.
- 205. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 205 of the Complaint, and, therefore, deny them.
- 206. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 206 of the Complaint, and, therefore, deny them.
- 207. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 207 of the Complaint, and, therefore, deny them.

## COUNT XXI - INFRINGEMENT OF THE '926 PATENT BY COBALT

- 208. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 207 of the Complaint as if fully set forth herein.
- 209. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 209 of the Complaint, and, therefore, deny them.

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- 210. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 210 of the Complaint, and, therefore, deny them.
- 211. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 211 of the Complaint, and, therefore, deny them.
- 212. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 212 of the Complaint, and, therefore, deny them.
- 213. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 213 of the Complaint, and, therefore, deny them.
- 214. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 214 of the Complaint, and, therefore, deny them.
- 215. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 215 of the Complaint, and, therefore, deny them.
- 216. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 216 of the Complaint, and, therefore, deny them.

## COUNT XXII - INFRINGEMENT OF THE '926 PATENT BY GLENMARK

- 217. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 216 of the Complaint as if fully set forth herein.
- 218. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 218 of the Complaint, and, therefore, deny them.
- 219. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 219 of the Complaint, and, therefore, deny them.
- 220. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 220 of the Complaint, and, therefore, deny them.
- 221. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 221 of the Complaint, and, therefore, deny them.
- 222. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 222 of the Complaint, and, therefore, deny them.
- 223. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 223 of the Complaint, and, therefore, deny them.

- 224. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 224 of the Complaint, and, therefore, deny them.
- 225. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 225 of the Complaint, and, therefore, deny them.

## COUNT XXIII - INFRINGEMENT OF THE '926 PATENT BY ORCHID

- 226. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 225 of the Complaint as if fully set forth herein.
- 227. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 227 of the Complaint, and, therefore, deny them.
- 228. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 228 of the Complaint, and, therefore, deny them.
- 229. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 229 of the Complaint, and, therefore, deny them.
- 230. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 230 of the Complaint, and, therefore, deny them.

- 231. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 231 of the Complaint, and, therefore, deny them.
- 232. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 232 of the Complaint, and, therefore, deny them.
- 233. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 233 of the Complaint, and, therefore, deny them.
- 234. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 234 of the Complaint, and, therefore, deny them.

## COUNT XXIV – INFRINGEMENT OF THE '926 PATENT BY LUPIN

- 235. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 234 of the Complaint as if fully set forth herein.
- 236. Defendants admit that ANDA No. 91-124 was submitted by Lupin Ltd. to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(j)), and that ANDA No. 91-124 seeks FDA approval for the commercial manufacture, use and sale of generic tablets containing 1 mg, 2 mg, or 3 mg of eszopiclone ("the ANDA products") prior to the expiration of the '926 patent. Defendants admit that ANDA No. 91-124 seeks to market the ANDA products prior to the expiration of the '926 patent, and that the ANDA contained a certification with respect to that patent. Defendants deny the remaining allegations set forth in paragraph 236 of the complaint.

- 237. Defendants admit that ANDA No. 91-124 contains a certification pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '926 patent are either invalid or will not be infringed by the manufacture, use or sale of the proposed generic versions of Sepracor's Lunesta® brand products. Defendants admit that on or about February 23, 2009, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Lupin Ltd. sent a statement to Sepracor, in which Lupin Ltd. represented that it had filed ANDA No. 91-124, seeking to market the ANDA Products prior to the expiration of the '926 patents, and that its ANDA contained a certification with respect to that patent. Defendants deny the remaining allegations set forth in paragraph 237 of the complaint.
  - 238. Defendants deny the allegations set forth in paragraph 238 of the complaint.
  - 239. Defendants deny the allegations set forth in paragraph 239 of the complaint.
  - 240. Defendants deny the allegations set forth in paragraph 240 of the complaint.
- 241. Defendants admit that at the time the certification in paragraph 237 was filed with the FDA, Lupin Ltd. and Lupin Pharma were aware of the existence of the '926 patent.

  Defendants deny the remaining allegations set forth in paragraph 241 of the complaint.
  - 242. Defendants deny the allegations set forth in paragraph 242 of the complaint.
  - 243. Defendants deny the allegations set forth in paragraph 243 of the complaint.

### COUNT XXV - INFRINGEMENT OF THE '926 PATENT BY SUN

- 244. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 243 of the Complaint as if fully set forth herein.
- 245. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 245 of the Complaint, and, therefore, deny them.

- 246. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 246 of the Complaint, and, therefore, deny them.
- 247. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 247 of the Complaint, and, therefore, deny them.
- 248. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 248 of the Complaint, and, therefore, deny them.
- 249. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 249 of the Complaint, and, therefore, deny them.
- 250. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 250 of the Complaint, and, therefore, deny them.
- 251. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 251 of the Complaint, and, therefore, deny them.
- 252. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 252 of the Complaint, and, therefore, deny them.

#### COUNT XXVI - INFRINGEMENT OF THE '926 PATENT BY ALPHAPHARM

- 253. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 252 of the Complaint as if fully set forth herein.
- 254. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 254 of the Complaint, and, therefore, deny them.
- 255. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 255 of the Complaint, and, therefore, deny them.
- 256. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 256 of the Complaint, and, therefore, deny them.
- 257. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 257 of the Complaint, and, therefore, deny them.
- 258. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 258 of the Complaint, and, therefore, deny them.
- 259. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 259 of the Complaint, and, therefore, deny them.

- 260. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 260 of the Complaint, and, therefore, deny them.
- 261. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 261 of the Complaint, and, therefore, deny them.

### Infringement of the '724 Patent

### COUNT XXVII - INFRINGEMENT OF THE '724 PATENT BY REDDY

- 262. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 261 of the Complaint as if fully set forth herein.
- 263. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 263 of the Complaint, and, therefore, deny them.
- 264. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 264 of the Complaint, and, therefore, deny them.
- 265. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 265 of the Complaint, and, therefore, deny them.
- 266. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 266 of the Complaint, and, therefore, deny them.

- 267. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 267 of the Complaint, and, therefore, deny them.
- 268. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 268 of the Complaint, and, therefore, deny them.
- 269. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 269 of the Complaint, and, therefore, deny them.
- 270. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 270 of the Complaint, and, therefore, deny them.

### COUNT XXVIII - INFRINGEMENT OF THE '724 PATENT BY ROXANE

- 271. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 270 of the Complaint as if fully set forth herein.
- 272. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 272 of the Complaint, and, therefore, deny them.
- 273. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 273 of the Complaint, and, therefore, deny them.

- 274. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 274 of the Complaint, and, therefore, dony them.
- 275. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 275 of the Complaint, and, therefore, deny them.
- 276. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 276 of the Complaint, and, therefore, deny them.
- 277. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 277 of the Complaint, and, therefore, deny them.

### COUNT XXIX - INFRINGEMENT OF THE '724 PATENT BY COBALT

- 278. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 277 of the Complaint as if fully set forth herein.
- 279. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 279 of the Complaint, and, therefore, deny them.
- 280. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 280 of the Complaint, and, therefore, deny them.

- 281. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 281 of the Complaint, and, therefore, deny them.
- 282. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 282 of the Complaint, and, therefore, deny them.
- 283. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 283 of the Complaint, and, therefore, deny them.
- 284. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 284 of the Complaint, and, therefore, deny them.
- 285. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 285 of the Complaint, and, therefore, deny them.
- 286. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 286 of the Complaint, and, therefore, deny them.

### COUNT XXX – INFRINGEMENT OF THE '724 PATENT BY GLENMARK

287. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 286 of the Complaint as if fully set forth herein.

- 288. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 288 of the Complaint, and, therefore, deny them.
- 289. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 289 of the Complaint, and, therefore, deny them.
- 290. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 290 of the Complaint, and, therefore, deny them.
- 291. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 291 of the Complaint, and, therefore, deny them.
- 292. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 292 of the Complaint, and, therefore, deny them.
- 293. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 293 of the Complaint, and, therefore, deny them.
- 294. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 294 of the Complaint, and, therefore, deny them.

295. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 295 of the Complaint, and, therefore, deny them.

### COUNT XXXI – INFRINGEMENT OF THE '724 PATENT BY ORCHID

- 296. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 295 of the Complaint as if fully set forth herein.
- 297. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 297 of the Complaint, and, therefore, deny them.
- 298. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 298 of the Complaint, and, therefore, deny them.
- 299. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 299 of the Complaint, and, therefore, deny them.
- 300. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 300 of the Complaint, and, therefore, deny them.
- 301. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 301 of the Complaint, and, therefore, deny them.

- 302. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 302 of the Complaint, and, therefore, deny them.
- 303. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 303 of the Complaint, and, therefore, deny them.
- 304. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 304 of the Complaint, and, therefore, deny them.

### COUNT XXXII – INFRINGEMENT OF THE '724 PATENT BY LUPIN

- 305. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 304 of the Complaint as if fully set forth herein.
- 306. Defendants admit that ANDA No. 91-124 was submitted by Lupin Ltd. to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(j)), and that ANDA No. 91-124 seeks FDA approval for the commercial manufacture, use and sale of generic tablets containing 1 mg, 2 mg, or 3 mg of eszopiclone ("the ANDA products") prior to the expiration of the '724 patent. Defendants admit that ANDA No. 91-124 seeks to market the ANDA products prior to the expiration of the '724 patent, and that the ANDA contained a certification with respect to that patent. Defendants deny the remaining allegations set forth in paragraph 306 of the complaint.
- 307. Defendants admit that ANDA No. 91-124 contains a certification pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '724 patent are either invalid or will not be infringed by the manufacture, use or sale of the proposed

generic versions of Sepracor's Lunesta® brand products. Defendants admit that on or about February 23, 2009, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Lupin Ltd. sent a statement to Sepracor, in which Lupin Ltd. represented that it had filed ANDA No. 91-124, seeking to market the ANDA Products prior to the expiration of the '724 patents, and that its ANDA contained a certification with respect to that patent. Defendants deny the remaining allegations set forth in paragraph 307 of the complaint.

- 308. Defendants deny the allegations set forth in paragraph 308 of the complaint.
- 309. Defendants deny the allegations set forth in paragraph 309 of the complaint.
- 310. Defendants deny the allegations set forth in paragraph 310 of the complaint.
- 311. Defendants admit that at the time the certification in paragraph 307 was filed with the FDA, Lupin Ltd. and Lupin Pharma were aware of the existence of the '724 patent.

  Defendants deny the remaining allegations set forth in paragraph 311 of the complaint.
  - 312. Defendants deny the allegations set forth in paragraph 312 of the complaint.
  - 313. Defendants deny the allegations set forth in paragraph 313 of the complaint.

### COUNT XXXIII – INFRINGEMENT OF THE '724 PATENT BY SUN

- 314. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 313 of the Complaint as if fully set forth herein.
- 315. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 315 of the Complaint, and, therefore, deny them.
- 316. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 316 of the Complaint, and, therefore, deny them.

- 317. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 317 of the Complaint, and, therefore, deny them.
- 318. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 318 of the Complaint, and, therefore, deny them.
- 319. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 319 of the Complaint, and, therefore, deny them.
- 320. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 320 of the Complaint, and, therefore, deny them.
- 321. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 321 of the Complaint, and, therefore, deny them.
- 322. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 322 of the Complaint, and, therefore, deny them.

### COUNT XXXIV – INFRINGEMENT OF THE '724 PATENT BY ALPHAPHARM

323. Defendants repeat and reassert their answers to the allegations set forth in paragraphs 1 through 322 of the Complaint as if fully set forth herein.

- 324. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 324 of the Complaint, and, therefore, deny them.
- 325. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 325 of the Complaint, and, therefore, deny them.
- 326. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 326 of the Complaint, and, therefore, deny them.
- 327. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 327 of the Complaint, and, therefore, deny them.
- 328. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 328 of the Complaint, and, therefore, deny them.
- 329. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 329 of the Complaint, and, therefore, deny them.
- 330. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 330 of the Complaint, and, therefore, deny them.

331. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 331 of the Complaint, and, therefore, deny them.

### Affirmative Defenses

Further responding to the Complaint, and as additional defenses thereto, Defendants assert the following affirmative defenses, without admitting any allegations of the Complaint not otherwise admitted and without assuming the burden when such burden would otherwise be on Plaintiffs.

# First Affirmative Defense (Invalidity of the '257 patent)

- 332. One or more claims of the '257 patent are invalid for failing to meet one or more conditions for patentability set forth in 35 U.S.C. § 101 et seq.
- 333. By way of example and not of limitation, one or more claims of the '257 patent are invalid under 35 U.S.C. §§ 102, 103, and/or 112.

# Second Affirmative Defense (Invalidity of the '673 patent)

- 334. One or more claims of the '673 patent are invalid for failing to meet one or more conditions for patentability set forth in 35 U.S.C. § 101 et seq.
- 335. By way of example and not of limitation, one or more claims of the '673 patent are invalid under 35 U.S.C. §§ 102, 103, and/or 112.

## Third Affirmative Defense (Invalidity of the '926 patent)

336. One or more claims of the '926 patent are invalid for failing to meet one or more conditions for patentability set forth in 35 U.S.C. § 101 et seq.

337. By way of example and not of limitation, one or more claims of the '926 patent are invalid under 35 U.S.C. §§ 102, 103, and/or 112.

### Fourth Affirmative Defense (Non-infringement of the '724 patent)

338. The manufacture, use, offer for sale, sale, or importation of Defendants' eszopiclone products that are the subject of ANDA 91-124 will not infringe any valid claim of the '724 patent.

## <u>Fifth Affirmative Defense</u> (Invalidity of the '724 patent)

- 339. One or more claims of the '724 patent are invalid for failing to meet one or more conditions for patentability set forth in 35 U.S.C. § 101 et seq.
- 340. By way of example and not of limitation, one or more claims of the '724 patent are invalid under 35 U.S.C. §§ 102, 103, and/or 112.

### Counterclaims

Further Responding to the Complaint, Defendants allege the following counterclaims against Sepracor ("Plaintiff"), without admitting any allegation of the Complaint not otherwise admitted, and without assuming the burden when such burden would otherwise be on Plaintiff.

#### The Parties

- 341. Lupin Ltd. is a corporation organized and existing under the laws of India and has a principal place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India.
- 342. Lupin Pharmaceuticals, Inc. ("Lupin Pharma") is a corporation organized and existing under the laws of Virginia and has a principal place of business at Harborplace Tower, 111 S. Calvert Street, 21st Floor, Baltimore, MD 21202, Unites States. Lupin Ltd. and Lupin Pharma are sometimes referred to herein collectively as "Defendants."

- 343. On information and belief, Sepracor is a corporation organized and existing under the laws of Delaware and has a principal place of business at 84 Waterford Drive, Marlborough, MA 01752, United States.
- 344. Upon information and belief, Sepracor is the holder of an approved new drug application ("NDA") 21-476 for eszopiclone tablets, marketed under the trademark Lunesta<sup>®</sup>.
- 345. Upon information and belief, based upon Sepracor's Complaint, Sepracor owns and asserts the rights to enforce U.S. Patent Nos. 6,864,257 ("the '257 patent"); 6,444,673 ("the '673 patent"); 6,319,926 ("the '926 patent"); and 7,381,724 ("the '724 patent").

### Jurisdiction and Venue

- 346. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), in that it involves substantial claims arising under the United States Patent Act, 35 U.S.C. § 1 et seq.
- 347. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because this is a case of actual controversy within the Court's jurisdiction seeking a declaratory judgment that the '257, '673, and '926 patents are invalid and that the '724 patent is not infringed and invalid.
  - 348. Venue is proper pursuant to 38 U.S.C. §§ 1391(b) and (c).

#### The Controversy

- 349. Defendants hold Abbreviated New Drug Application ("ANDA") No. 91-124 for eszopiclone tablets (1, 2, and 3 mg).
- 350. On or about March 20, 2009, Plaintiffs filed the present action against Defendants alleging infringement of the '257, '673, '926, and '724 patents arising from Defendants' submission of ANDA No. 91-124.

## Counterclaim Count 1 Declaratory Judgment of Non-infringement of the '724 Patent

- 351. Defendants repeat and incorporate by reference paragraphs 341-350.
- 352. The manufacture, use, offer for sale, sale or importation of Defendants' eszopiclone products that are the subject of ANDA 91-124 will not infringe any valid claim of the '724 patent.
- 353. Defendants have not infringed the '724 patent by filing ANDA 91-124 because the manufacture, use, offer for sale, sale, or importation of Defendants' eszopiclone products that are the subject of ANDA 91-124 will not infringe any valid claim of the '724 patents.
- 354. Because Defendants have not infringed and will not infringe any valid claim of the '724 patent, Plaintiffs are entitled to no damages or other relief from or against Defendants for any such infringement.

# Counterclaim Count II Declaratory Judgment of Invalidity of the '926 Patent

- 355. Defendants repeat and incorporate by reference paragraph 341-354.
- 356. One or more claims of the '926 patent are invalid for failing to meet one or more conditions for patentability set forth in 35 U.S.C. § 101 et seq. By way of example, and not of limitation, one or more claims of the '926 patent are invalid under 35 U.S.C. § 102.

# Counterclaim Count III Declaratory Judgment of Invalidity of the '257 Patent

- 357. Defendants repeat and incorporate by reference paragraph 341-356.
- 358. One or more claims of the '257 patent are invalid for failing to meet one or more conditions for patentability set forth in 35 U.S.C. § 101 et seq. By way of example, and not of limitation, one or more claims of the '257 patent are invalid under 35 U.S.C. § 102.

# Counterclaim Count IV Declaratory Judgment of Invalidity of the '673 Patent

- 359. Defendants repeat and incorporate by reference paragraph 341-358.
- 360. One or more claims of the '673 patent are invalid for failing to meet one or more conditions for patentability set forth in 35 U.S.C. § 101 *et seq*. By way of example, and not of limitation, one or more claims of the '673 patent are invalid under 35 U.S.C. § 103.

### Counterclaim Count V Declaratory Judgment of Invalidity of the '724 Patent

- 362. Defendants repeat and incorporate by reference paragraph 341-361.
- 363. One or more claims of the '724 patent are invalid for failing to meet one or more conditions for patentability set forth in 35 U.S.C. § 101 *et seq.* By way of example, and not of limitation, one or more claims of the '724 patent are invalid under 35 U.S.C. § 102.

### Praver for Relief

WHEREFORE, Defendants seek judgment against Plaintiff as follows:

- A. That Plaintiff's Complaint, and all of its causes of action against the Lupin Defendants, be dismissed with prejudice.
- B. That judgment be entered in favor of Defendants, including an Order adjudging
   U.S. Patent No. 6,864,257 invalid and declaring this an exceptional case;
- C. That judgment be entered in favor of Defendants, including an Order adjudging U.S. Patent No. 6,444,673 invalid and declaring this an exceptional case;
- D. That judgment be entered in favor of Defendants, including an Order adjudging U.S. Patent No. 6,319,926 invalid and declaring this an exceptional case;
- E. That judgment be entered in favor of Defendants, including an Order adjudging U.S. Patent No. 7,381,724 invalid and not infringed by Defendants, and declaring this an exceptional case;

- F. That Defendants be awarded its fees and costs in defending this litigation pursuant to 35. U.S.C. § 285; and
- G. That Defendants be awarded such other and further relief as the Court deems just and proper.

Dated: May 5, 2009

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Of Counsel

By: /s/ Karen A. Confoy

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Attorneys for Defendants Lupin Pharmaceuticals, Inc. and Lupin Ltd.

Case 2:09-cv-01302-DMC -MF Document 32 Filed 05/05/09 Page 56 of 57 PageID: 672

CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

Pursuant to Local Rules 11.2 and 40.1, the undersigned counsel for Defendants Lupin

Ltd. and Lupin Pharmaceuticals, Inc. certifies that, to the best of her knowledge, information and

belief, the matter in controversy is not the subject of any other action or proceeding.

/s/ Karen A. Confoy

Karen A. Confoy

Dated: May 5, 2009

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, the undersigned counsel for Defendants Lupin Ltd.

and Lupin Pharmaceuticals, Inc. certifies Lupin's causes of action as asserted in its

counterclaims seek primarily declaratory judgment relief. This action is, therefore, not

appropriate for compulsory arbitration.

/s/ Karen A. Confoy

Karen A. Confoy

Dated: May 5, 2009

56

### **CERTIFICATION OF SERVICE**

The undersigned attorney certifies that she caused a copy of the foregoing Answer, Affirmative Defenses, and Counterclaims to be served by electronic mail on the 5<sup>th</sup> day of May, 2009 upon:

Charles M. Lizza
William C. Baton
Saul Ewing
One Riverfront Plaza
Newark, New Jersey 07102

/s/ Karen A. Confoy
Karen A. Confoy

Dated: May 5, 2009